Effective February 1, 2019

Chemotherapy

J9153, J9229, Q5107

J9153

Daunorubicin and cytarabine liposome is used for the treatment of patients 18 years of age and older with newly-diagnosed, therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary to treat t-AML or AML-MRC.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/chemotherapy order for daunorubicin/cytarabine liposome.

Modifiers SA, UD, U7 and 99 are allowed.

J9229

Inotuzumab ozogamicin is used for the treatment of patients 18 years of age and older with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

An approved TAR is required for reimbursement. The TAR must include clinical documentation that demonstrates the following:

- The service is medically necessary to treat relapsed or refractory B-cell precursor ALL.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/chemotherapy order for inotuzumab ozogamicin.

Modifiers SA, UD, U7 and 99 are allowed.

Q5107

Bevacizumab-awwb is indicated for the treatment of patients 18 years of age and older and is used to treat the following conditions:

- Colorectal cancer, metastatic
- Non-small cell lung cancer, unresectable
- Glioblastoma, recurrent
- Renal cell carcinoma, metastatic
- Ovarian cancer

An approved TAR is required for reimbursement. The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/chemotherapy order for bevacizumab-awwb.

Modifiers SA, UD, U7, 99, RT and LT are allowed.

Injections

J0584, J0599, J2186, J3245, J3397, J7177

J0584

Burosumab-twza is indicated for the treatment of patients 1 year of age and older with X-linked hypophosphatemia (XLH).

An approved TAR is required for reimbursement. The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary to treat XLH.
- A confirmed diagnosis of XLH as documented by one of the following:
  - Laboratory values including low serum phosphate concentration, a reduced TmP/FGR based on normative values for age, and an inappropriate level of calcitriol for the level of hypophosphatemia.
  - A low serum phosphate concentration with increased alkaline phosphatase activity in a patient at risk for XLH due to family history with an appropriate X-linked inheritance pattern.
  - Abnormal fibroblast growth factor 23 (FGF23) levels consistent with XLH with an appropriate X-linked inheritance pattern.
  - Molecular genetic testing of a PHEX (Phosphate-regulating Endopeptidase Homolog, X-linked) pathogenic variant in the patient or in a directly related family member with an appropriate X-linked inheritance pattern.
- The patient's baseline fasting serum phosphorus is below the normal range for age.
- The patient does not have severe renal impairment or end stage renal disease.
- The patient will not receive concurrent treatment with oral phosphate or active vitamin D analogs.
- For continued treatment authorization, the patient's current serum phosphorous level is not above the upper limit of the laboratory normal reference range.
- The physician's legible, complete, and signed treatment plan/order for burosumab-twza.

ICD-10-CM diagnosis code E83.31 is required for reimbursement.

Modifiers SA, UD, U7 and 99 are allowed.

J0599
C1-INH is indicated for the treatment of patients 12 years of age and older and is used for routine, long-term prophylaxis to prevent hereditary angioedema (HAE or inherited C1 inhibitor [C1-INH] deficiency) attacks.

An approved TAR is required for reimbursement. The TAR should include clinical documentation that demonstrates all of the following:

1. Either:
   a) A confirmed diagnosis of HAE as documented by a monoallelic mutation known to cause HAE in either the SERPING1 or F12 gene or
   b) A C4 level below the lower limit of the normal reference range as defined by the laboratory performing the test and any one of the following:
      - ❖ A C1 INH antigenic level below the lower limit of the normal reference range as defined by the laboratory performing the test.
      - ❖ A C1 INH functional level below the lower limit of the normal reference range as defined by the laboratory performing the test.
2. There is a history of at least one moderate or severe angioedema attack per month (e.g. airway swelling, facial edema or painful distortion, abdominal pain, etc.).
3. Medications known to trigger angioedema attacks have been evaluated and discontinued when appropriate.
4. C1 esterase inhibitor (human) (Haegarda) will not be administered in conjunction with other approved treatments for acute HAE attacks.
5. Alternative long-term prophylaxis treatments have been tried or considered, have failed, or are contraindicated.
6. The physician's legible, complete, and signed treatment plan/order for C1 esterase inhibitor (human) as a routine prophylaxis against HAE attacks or as a short-term prophylaxis prior to surgery, dental procedures, or intubation.

ICD-10-CM diagnosis code D84.1 is required for reimbursement.

Modifiers SA, UD, U7 and 99 are allowed.

J2186
Meropenem and vaborbactam are indicated for the treatment of patients 18 years of age and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by susceptible bacterial microorganism such as *Escherichia coli*, *Klebsiella pneumonia*, and *Enterobacter cloacae species* complex.

An approved TAR is required for reimbursement. The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary to treat a complicated urinary tract infection (cUTI) including pyelonephritis caused by a susceptible bacterial microorganism such as *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae species* complex, based on urine or blood culture and sensitivity reporting.
- The patient's eGFR measurement.
- Alternative treatments have been tried or considered, have failed, or are contraindicated.
- The physician's legible, complete, and signed treatment plan/order for meropenem and vaborbactam.

Modifiers SA, UD, U7 and 99 are allowed.

J3245
Tildrakizumab-asmn is indicated for the treatment of patients 18 years of age and older with moderate-to-severe chronic plaque psoriasis (i.e. extensive and/or disabling disease) who are candidates for phototherapy or systemic therapy and when other systemic therapies are medically less appropriate.

An approved TAR is required for reimbursement. The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary to treat patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate.
- Alternative psoriasis therapies (e.g. phototherapy, oral agents, etc.) have been tried or considered, have failed, or are contra-indicated.
- The physician's legible, complete, and signed treatment plan/order for tildrakizumab-asmn.

Modifiers SA, UD, U7 and 99 are allowed.

J3397
Vestronidase alfa-vjbk is indicated for the treatment of patients of all ages with Mucopolysaccharidosis VII (MPS VII or "Sly Syndrome").

An approved TAR is required for reimbursement. The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary to treat MPS VII.
- Additional criteria listed under the "Enzyme Replacement Drugs," "Authorization" subheading in the *Injections: Drugs E-H Policy* manual section.
- The physician's legible, complete, and signed treatment plan/order for vestronidase alfa-vjbk.

ICD-10-CM diagnosis code E76.29 is required on the claim.

Modifiers SA, UD, U7 and 99 are allowed.

J7177
Fibrinogen (human) is indicated for the treatment of patients 12 years of age and older with acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

An approved TAR is required for reimbursement. The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary to treat an acute bleeding episode in a patient with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.
- The plasma fibrinogen levels and bleeding assessments taken and monitored during fibrinogen treatment.
- The physician's legible, complete, and signed treatment plan/order for fibrinogen (human) concentrate (Fibryga®).

ICD-10-CM diagnosis code D68.2 is required on the claim.

Modifiers SA, UD, U7 and 99 are allowed.

Physician Administered Drugs

C9407, C9408

C9407
Treatment with HCPCS code C9407 is restricted to patients 12 years of age and older. Modifiers SA, UD, U7 and 99 are allowed.

C9408
Iobenguane I-131 is used for the treatment of patients 12 years of age and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.

An approved TAR is required for reimbursement. The TAR should include clinical documentation that demonstrates the following:

- The service is medically necessary to treat iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.
- The physician's legible, complete, and signed treatment plan/order for Iodine I-131 iobenguane therapeutic injection.

Modifiers SA, UD, U7 and 99 are allowed.